

# EXHIBIT 2



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## 510(k) Premarket Notification



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**Device Classification Name** [system, test, blood glucose, over the counter](#)<sup>22</sup>  
**510(k) Number** K160944  
**Device Name** ACCU-CHEK Guide Blood Glucose Monitoring System  
**Applicant** Roche Diabetes Care, Inc.  
 9115 Hague Road  
 Indianapolis, IN 46250 -0457  
**Applicant Contact** Khone Saysana  
**Correspondent** Roche Diabetes Care, Inc.  
 9115 Hague Road  
 Indianapolis, IN 46250 -0457  
**Correspondent Contact** Khone Saysana  
**Regulation Number** [862.1345](#)<sup>23</sup>  
**Classification Product Code** [NBW](#)<sup>24</sup>  
**Subsequent Product Codes** [JJX](#)<sup>25</sup> [LFR](#)<sup>26</sup>  
**Date Received** 04/05/2016  
**Decision Date** 08/31/2016  
**Decision** Substantially Equivalent (SESE)  
**Regulation Medical Specialty** Clinical Chemistry  
**510k Review Panel** Clinical Chemistry  
**Summary** [Summary](#)<sup>27</sup>  
**FDA Review** [Decision Summary](#)<sup>28</sup>  
**Type** Traditional  
**Reviewed by Third Party** No  
**Combination Product** No  
**Recalls** [CDRH Recalls](#)<sup>29</sup>

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Page Last Updated: 05/06/2024

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Silver Spring, MD 20993  
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